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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,907	04/20/2004	Michael T. Barrett	10031034-1	5662

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	**PAPER NUMBER**
1634	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,907	BARRETT ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *17-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed 28 February 2007 in which claim 1 was amended. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 30 November 2006 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

The examiner for this application has changed. Please address future correspondence to Examiner BJ Forman, Art Unit: 1634.

Claims 1-16 are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1-16 are indefinite in Claim 1 for the recitation "synthesized by mixing per-determined amounts of individual chromosomes" because it is unclear whether the recitation defines a method step. The nucleic acids used in the method are defines as made from a non-cellular chromosome composition. Because the claim merely requires a first population of 2 nucleic acids, which are made from the composition, it is unclear how, if, or whether the syntheses of the composition from which the probes are made further define the method.

Claim 1-16 are indefinite in Claim 1 for the recitation "with an array of surface-bound polynucleotides" because it is unclear whether the recitation defines the synthesis or the contacting.

Claim 3-5 are indefinite in Claim 3 because it is drawn to binding between the probe and chromosome in the non-cellular composition. The method of Claim 1 defines binding between the probe a nucleic acids "**made from** a non-cellular chromosome composition". Hence, chromosome binding does not occur in the method. Therefore the chromosome binding analysis of Claim 3 lacks proper antecedent basis in Claim 1.

Claims 4-5 are indefinite in Claim 4. Similar to Claim 3 above, Claim 4 is drawn to the presence of chromosomes. However, only nucleic acids made from chromosomes are defined in Claim 1. Therefore the chromosomes of Claim 4 lack proper antecedent basis in Claim 1. Claim 4 is further indefinite because in is unclear which chromosome is defined by the recitation "said chromosome".

Claims 4-8 are each indefinite because they define the chromosome composition from which the nucleic acids of Claim 1 are made. The method of Claim 1 does not define a numerical and/or structural relationship between the chromosomal composition and nucleic acids "made" such that the defining limitations defining the chromosomes further define the method of Claim 1. For example, the method of Claim 1 merely requires nucleic acids be made from a chromosomal composition, the composition synthesized by mixing known amounts of chromosomes. However, the claim does not require making nucleic acids from each chromosome of the composition. The claim merely requires that the composition be used to make the nucleic acids. As such, the number of chromosomes in the composition do not further define the method of Claim 1.

Claim 15 is indefinite for the recitation "chromosome composition probes comprising all chromosomes" because it is unclear whether "comprising all chromosomes" defines the probes or the chromosome composition.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-16 are rejected under 35 U.S.C. 102(a) as being anticipated by Lucito et al (Genome Research, published 15 September 2003, 13: 2291-2305).

Regarding Claim 1, Lucito et al disclose a method of assessing a surface-bound probe (Abstract), the method comprising contacting first and second labeled populations of nucleic acids with the surface bound probes and evaluating the binding of the probes to the labeled populations (pages 2295-2298, Fig. 2-3). Lucito teach the method wherein labeled population is made from non-cellular chromosome composition synthesized by mixing predetermined amounts of individual chromosomes (page 2304, first paragraph).

Regarding Claim 2, Lucito et al disclose the method wherein the labeled populations are distinguishably labeled (page 2304, first paragraph).

Regarding Claim 3, Lucito et al disclose the method wherein the test and reference population bind to the same surface-bound probe (Fig. 3-4).

Regarding Claim 4-5, Lucito et al disclose the method wherein the chromosomes of the composition are present in a pre-determined ratio of whole numbers e.g. X-chromosome (Fig. 3D).

Regarding Claim 6, Lucito et al disclose the method wherein the chromosomes are human (pages 2295-2298, Fig. 2-4).

Regarding Claims 7-8, Lucito et al disclose the method wherein at least one chromosome of the composition is at a level not naturally occurring in nature (i.e. aneuploid) and the composition comprise all chromosomes i.e. 1 through Y (Fig. 2).

Regarding Claim 9, Lucito et al disclose the method wherein the surface-bound probe is an oligonucleotide (page 2303, right column).

Regarding Claim 10, Lucito et al disclose the method further comprising isolating chromosomes from mammalian cells to provide the chromosomal composition (page 2295, right column, first full paragraph).

Regarding Claim 11, Lucito et al disclose the method of Claim 1 wherein candidate probe are evaluated for use in array-base hybridization (Abstract, pages 2293-2298).

Regarding Claim 12, Lucito et al disclose the method wherein the probe that binds to the first and second population corresponds to the level of chromosomes in the compositions (pages 2293-2298).

Regarding Claim 13, Lucito et al disclose the method wherein the chromosome is a predetermined chromosome e.g. X (Fig. 3D).

Regarding Claim 14, Lucito et al disclose the method wherein the array comprises a plurality of different probes (page 2293, left column and page 2302, right column).

Regarding Claim 15, Lucito et al disclose the method wherein the chromosome composition comprise all chromosomes (page 2293, left column and page 2302, right column).

Regarding Claim 16, Lucito et al disclose the method further comprising identifying probes suitable for use in array-based comparative hybridization (Abstract, page 2293 and page 2302, right column).

6. Claims 1-9, 11, 14, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Buchard (WO 01/06013, published 25 January 2001).

Regarding Claim 1, Buchard discloses a method of assessing a surface-bound probe (Abstract), the method comprising contacting first and second labeled populations of nucleic acids with the surface bound probes and evaluating the binding of the probes to the labeled populations (Claims 1-19, Fig. 1). Buchard teaches the method wherein labeled population is made from non-cellular chromosome composition (i.e. genomic DNA, page 14, lines 15-28) synthesized by mixing predetermined amounts of individual chromosomes (i.e. the target nucleic acids are synthesized enzymatically from samples present in known amount or abundance, pages 27-35).

Regarding Claim 2, Buchard discloses the method wherein the labeled populations are distinguishably labeled (page 35, lines 34-36).

Regarding Claim 3, Buchard teaches the method wherein the test and reference population bind to the same surface-bound probe (pages 36-37).

Regarding Claim 4-5, Buchard teaches the method wherein the chromosomes of the composition are present in a pre-determined ratio of whole numbers (page 14, lines 15-28).

Regarding Claim 6, Buchard teaches the method wherein the chromosomes are human (page 15, lines 21-24).

Regarding Claims 7-8, Buchard discloses the method wherein at least one chromosome of the composition is at a level not naturally occurring in nature and the composition comprise all chromosomes (e.g. deletion strain from a bacterial cell, page 15, lines 16-20).

Regarding Claim 9, Buchard discloses the method wherein the surface-bound probe is an oligonucleotide (Abstract).

Regarding Claim 11, Buchard discloses the method of Claim 1 wherein candidate probe are evaluated for use in array-base hybridization (Abstract).

Regarding Claim 14, Buchard discloses the method wherein the array comprises a plurality of different probes (Abstract).

Regarding Claim 16, Buchard discloses the method further comprising identifying probes suitable for use in array-based comparative hybridization (Abstract, page 2293 and page 2302, right column).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snijders et al (Nature Genetics, 2001, 29: 263-264) in view of Buchard (WO 01/06013, published 25 January 2001).

Regarding Claims 1-16, Snijders et al teach a method of assessing probes on a support by contacting the probe with labeled nucleic acids made from test and control chromosome samples (Fig. 1) wherein the chromosomes are human, present in a predetermined amount (genome wide screening of tumor cells compared to normal. Snijders et al teach the method very similar to that claimed but are silent regarding the evaluation and/or analysis of the surface bound probes. However, this technique was well known and routinely practiced in the art of probe selection as defined by Buchard (as cited above). Buchard also teach the method of probe screening against defined target populations (control and test) provides probes that are optimized for sensitivity and specificity for a target. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the probe evaluation of Buchard to the chromosomal targets of Snijders. One of ordinary skill in the art would have been motivated to do so for the expected benefit of obtaining probes that are

optimized for sensitivity and specificity for targets (e.g. chromosomes) of interest as taught by Buchard (Abstract).

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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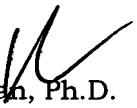
For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



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Primary Examiner
Art Unit: 1634
August 30, 2007